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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,103	09/12/2003	Parminder Singh	2335-0008.22	6566

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MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,103	SINGH ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment and request for RCE, both filed 05/17/2007.

Claims 1-59 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/17/2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 5-8, 10, 11, 27-36, 39 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,552,751 (751).

Claim 1 is directed to composition comprising

(1) composition comprising: (a) water swellable polymer, (b) hydrophilic polymer, and (c) oligomer; and

(2) erodible backing.

Claim 50 is directed to method of whitening teeth comprising using said composition.

US '751 disclosed multilayered film preparation that dissolves in body fluid, the film comprises layer comprises 10-80% water soluble polymer, 10-80% water insoluble polymer, 10-30% plasticizer that reads on the claimed oligomer, and drug, and other layer comprises hydroxypropyl cellulose or ethyl cellulose, which reads on the erodible backing layer (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51). The water soluble polymer comprises cellulose acetate, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol, all currently claimed as oligomer (col.2, lines 12-28). The erosion of the layer made of water insoluble polymer is inherently slower than layer containing water soluble polymers. The time of erosion of the multilayered film is inherent according to the percentage of water soluble, water insoluble, and plasticizers. The ability of the film to absorb water is inherent. Further, the layer that comprises water soluble polymer, water insoluble polymer, and plasticizer in the same ranges as claimed by applicants, such a layer is inherently hydrogel.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,800,832 ('832) in view of US 4,552,751 ('571).

US '832 teaches erodible pharmaceutical device for application to the mucosal surface, the device comprising one adhesive layer and backing layer (abstract). Both layers are water soluble (col.3, lines 28-33). The adhesive layer comprises one polymer selected from cellulose derivatives, which is water swellable polymer, combined with polymer selected from polyacrylic acid or polyvinyl pyrrolidone, which is water soluble

polymer (col.3, lines 34-39; col.5, lines 37-60; example 11). The backing layer comprises hydroxyethyl cellulose, hydroxypropyl cellulose or hydroxypropylmethyl cellulose (col.3, lines 40-45). The residence time of the device depends on the dissolution rate of the water soluble polymers, and the dissolution rate may be adjusted by adjusting the mixed amounts of the polymers, therefore the erosion time of the device claimed by claims 29-36 are expected to be obtained by adjusting the ratios of water soluble and water swellable polymers according to specific intended use (col.4, line 66-col.4, line 5). The film may contain therapeutic agent, flavoring agent and coloring agent (col.7, line6-col.8, line 10). The film contains water, i.e. hydrogel, or can be solid (col.11, table 1, lines 66-67). The device is expected to be capable to absorb water since it contains water swellable materials.

Although US '832 suggested oligomer in backing layer, col.6, lines 63-66, however, US '832 does not teach the oligomer in the adhesive layer as claimed by claim1, specific cellulose esters claimed by claims 3 and 11, materials of the backing layer other than cellulose as claimed by claims 12-14.

The specific cellulose esters claimed by claims 3 and 11 and the materials of the backing claimed by claims 12-14 do not impart patentability to the claims, absent evidence to the contrary. In any events, US '571 teaches cellulose acetate in dissolvable films, which is the cellulose ester claimed by claims 3 and 11.

US '571 teaches multilayered film preparation that dissolves in body fluid, the film comprises layer comprises 10-80% water soluble polymer, 10-80% water insoluble polymer, 10-30% plasticizer that reads on oligomer, and drug, and other layer

comprises hydroxypropyl cellulose or ethyl cellulose (abstract; col.2, lines 66-68; col.4, lines 59-55-63; col.6, lines 20-33, 49-51). The plasticizers, i.e. oligomers, have the advantage of providing soft flexible film and eliminating the disadvantage of physical properties at the administration site by enhancing the release properties of the active agent (col.4, lines 28-37). The water soluble polymer comprises cellulose acetate, hydroxypropyl cellulose and polyvinyl pyrrolidone; the water insoluble polymer comprises cellulose acetate; and the plasticizer include ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol (col.2, lines 12-28).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer and water soluble polymer as disclosed by US '832, and further add 10-30 % of plasticizer selected from ethylene glycol, propylene glycol, polyethylene glycol or polypropylene glycol as disclosed by US '751, motivated by the teaching of US '751 that such plasticizers have the advantage of providing soft flexible film and eliminating the disadvantage of physical properties at the administration site by enhancing the release properties of the active agent, with reasonable expectation of having erodible pharmaceutical device for application to the mucosal surface comprising adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer, wherein the device is soft, flexible and has enhanced release properties of the contained active agents.

7. Claims 42-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '832 and US '751, and further in view of US 5,891,453 ('453).

The combined teachings of US '832 and US '751 are discussed above. However, the combined teachings of the references do not teach teeth whitening material as claimed by claims 42-49, and teeth whitening method as claimed by claims 50-59.

US '453 teaches strip for teeth whitening comprising gel comprising tooth whitening active selected from the group consisting of peroxides, metal chlorites, perborates, percarbonates, peroxyacids, and combination thereof (abstract, examples, claim 8).

Hence, the combined teachings of US '832 and US '751 desired to deliver active agent to the mucus membranes and also provided enhanced delivery.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide erodible pharmaceutical device for application to the mucosal surface comprising active agent in adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer as disclosed by the combined teaching of US '832 and US '751, and replace the active agent by teeth whitening agent selected from peroxides and metal chlorites as disclosed by US '453, because US '453 teaches such materials as preferred material for tooth whitening for inclusion in gel strips applied to the mucus membrane, with reasonable expectation of having erodible pharmaceutical device for application to the mucosal surface comprising peroxide or metal chlorite in adhesive layer comprising water swellable polymer, water soluble polymer and plasticizer, that whiten the teeth effectively and safely with great success.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali

ISIS GHALI
PRIMARY EXAMINER